

**ELECTRONIC FILING**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Pettis *et al.*

Confirmation No.: 7814

Application No.: 09/606,909

Group Art Unit: 3767

Filed: June 29, 2000

Examiner: Witczak, Catherine

For: INTRADERMAL DELIVERY OF  
SUBSTANCES

Attorney Docket No.: 11219-008-999  
(P-4901)

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the continuing duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the United States Patent and Trademark Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application which are or may be material to patentability of any claim of the application, Applicants hereby direct the Examiner's attention to references **A39-A51**, **B06-B08** and **C17-C25** listed on the accompanying List of References Cited by Applicant.

Enclosures accompanying this Information Disclosure Statement are the following:

1. A List of References Cited by Applicant listing References **A39-A51**, **B06-B08** and **C17-C25** ; and
2. Copies of References **A47-A51**, **B06-B08** and **C17-C25** .

Pursuant to 37 C.F.R. § 1.98 (a)(2)(i), copies of references **A39-A46** are not submitted herewith because they are U.S. Patents or U.S. patent application publications.

**References B06-B08 and C17-C23**

Reference **B06** is European Patent No. EP 1 296 740 B1, which was granted from a European application which claims the priority of the subject application. Reference **C17** is a copy of the Communication of a Notice of Opposition from the European Patent Office dated July 18, 2008 in connection with an opposition filed to EP 1 296 740 B1 (Reference **B06**).

The July EPO Notice lists Documents “D1-D14.” Copies of Documents D5-D7, D9, D10, and D12-D14 are submitted herewith. The following chart correlates the reference numbers for documents D5-D7, D9, D10, and D12-D14 cited in the July EPO Notice with the corresponding reference numbers in the accompanying List of References Cited by Applicant.

<b>Reference No. in July EPO Notice for Opposition to EP 1 296 740 B1</b>	<b>Reference No. in the accompanying List of References Cited by Applicants</b>
D5 (Product Brochure of TERUMO Insulin Syringe)	<b>C18</b>
D6 (ISO 9626 – Table 2)	<b>C19</b>
D7 (Decision in EP 1 296 742)	<b>C20</b>
D9 (WO 93/17754)	<b>B07</b>
D10 (WO 00/16833)	<b>B08</b>
D12 (first page of Lantus’ draft product insert)	<b>C21</b>
D13 (Microgroup’s Stock Hypodermic Tubing Table)	<b>C22</b>
D14 (p. 192 of article in Dermatological Therapy)	<b>C23</b>

The undersigned notes that Applicants have already made Documents D1-D4, D8, and D11 cited in the July EPO Notice of record in the subject application. In particular, the following chart correlates the reference numbers for documents D1-D4, D8, and D11 cited in the July EPO Notice with the corresponding reference numbers of the documents already made of record in the subject application.

<b>Reference No. in July EPO Notice for Opposition to EP 1 296 740 B1</b>	<b>Reference No. in the Subject Application Cited by Applicants</b>
D1 (JP H01-13862 with English translation)	<b>B04</b> (IDS submitted June 18, 2007)
D2 (U.S. Patent No. 5,848,991)	Undesignated (IDS submitted June 29, 2000)
D3 (U.S. Patent No. 5,997,501)	<b>D</b> (PTO-892 with Office Action mailed April 26, 2002)
D4 (EP 692 270)	<b>B05</b> (IDS submitted June 18, 2007)
D8 (EP 429 842)	<b>EP</b> (IDS submitted December 18, 2002)
D11 (EP 1 092 444)	<b>BC</b> (IDS submitted November 12, 2002)

### **References C24 and C25**

Reference **C24** is a copy of the Communication of a Notice of Opposition from the European Patent Office dated August 14, 2008 (the “August EPO Notice”) in connection with an opposition filed to EP 1 296 740 B1 (Reference **B06**).

The August EPO Notice lists Documents lists “D1-D5.” A copy of Document D2 (L. Tuft *et al.*, Journal of Laboratory and Clinical Medicine) is submitted herewith as reference **C25** on the accompanying List of References Cited by Applicant.

The undersigned notes that Documents D3 (Brochure of TERUMO Insulin Syringe with Needle) and D5 (ISO 9626 – Table 2) are listed on the accompanying List of References Cited by Applicant as **C18** and **C19**, respectively.

Applicants have already made Documents D1 and D4 cited in the August EPO Notice of record in the subject application. The following chart correlates the reference numbers for documents D1 and D4 cited in the August EPO Notice with the corresponding reference numbers of the documents already made of record in the subject application.

<b>Reference No. in August EPO Notice for to EP 1 296 740 B1</b>	<b>Reference No. in the Subject Application (Cited by Applicants)</b>
D1 (U.S. Patent No. 5,848,991)	Undesignated (IDS submitted June 29, 2000)
D4 (U.S. 2003/0100885 A1)	<b>A08</b> (IDS submitted December 22, 2006)

### **References A49-A51**

References **A49-A51** are copies of Office Actions in Appl. Serial Nos. 11/004,778; 11/004,779, and 11/004,780; all of which are assigned to the assignee of the subject application.

Identification of the listed references is not to be construed as an admission of Applicants that such references are available as “prior art” against the subject application.

Applicants respectfully request that the Examiner review the listed references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b), since this Supplemental Information Disclosure Statement is being filed after the filing of a request for continued examination under § 1.114, no fee is due in connection with this submission. However, should the Patent and Trademark Office determine otherwise, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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Enclosures